Atty. Dkt. No. 050251-0150

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Looper et al.

Title: SURGICAL DEVICE WITH MALLEABLE SHAFT

Appl. No.: 09/785,374

Filing Date: 16 February 2001

Examiner: M. Patel

Art Unit: 3743

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231, on the date below.

Christine Kozich
(Printed Name)

(Signature)

March 3, 2004
(Date of Deposit)

APPEAL BRIEF TRANSMITTAL

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is the Appeal Brief, in triplicate, filed in response to the Final Rejection dated 8 October 2003 for the above-identified application.

A check in the amount of $330 is enclosed to cover the cost of submitting this Appeal. Additionally, the Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 06-1450.

Please direct all correspondence to the undersigned attorney or agent at the address indicated below.

Respectfully submitted,

Date: 3-3-04

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

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Christine Kozlok
(Printed Name)

Christine Kozlok
(Signature)

March 3, 2005
(Date of Deposit)

BRIEF ON APPEAL

Commissioner for Patents
PO Box 1450
Alexandria, Virginia 22313-1450

Sir:

Under the provisions of 37 C.F.R. § 1.192, this Appeal Brief is being filed in triplicate together with a check in the amount of $330.00 covering the Rule 17(c) appeal fee. If this fee is deemed to be insufficient, authorization is hereby given to charge any deficiency (or credit any balance) to the undersigned deposit account 06-1450.

REAL PARTY IN INTEREST

Allegiance Corporation

RELATED APPEALS AND INTERFERENCES

No pending related appeals or interferences.

STATUS OF CLAIMS

Claim 1, 3-13, 15-24, 26-31, 33-37, 39-43, and 45-89 are currently pending in the application. Of those claims, claims 22-24, 26-31, 33-37, 39-43, and 45-89 have been withdrawn from consideration. The remaining pending claims 1, 3-13, and 15-21 were finally rejected by the Examiner in an Office Action dated 8 October 2003.

STATUS OF AMENDMENTS

There are currently no outstanding amendments in the application.

SUMMARY OF INVENTION

The present invention provides a surgical device having a tissue engaging portion, a shaft member, and a handle assembly. The tissue engaging portion includes first and second opposed jaws for grasping, securing, and occluding body tissue and conduits. The shaft member is operatively coupled to the tissue engaging portion and is malleable. The shaft member is configured to be kink resistant and to bend about some bending radius in response to an applied bending moment. The handle assembly is operatively coupled to both the shaft member and to the tissue engaging portion. The shaft member of the present invention allows the surgeon to bend and adjust the shape of the surgical device to minimize its intrusion and to allow for proper positioning in predetermined body locations.

ISSUES

Whether the invention as claimed in 1, 3-13, and 15-21 would have been obvious at the time of the invention under 35 U.S.C. § 103(a) in view of U.S. Patent No. 5,474,057 issued to Makower et al?

GROUPING OF CLAIMS

Group I – Claims 1, 3-13, and 15-21.

ARGUMENT

Background

The present application was filed on 16 February 2001 with 52 claims as a continuation-in-part of issued U.S. Patent No. 6,139,563. In the first Office Action mailed on 6 August 2001, claims 1, 5, 6, 8 – 13, 16 – 24, 26 – 31, 33 – 38, and 40 - 43 were rejected under 35 U.S.C. §

102(b) as being anticipated by U.S. Patent No. 4,945,920 to Clossick; claims 2 – 4, 7, 14, 15, 25, 32, 38, 39, and 44 were objected to as being dependent on a rejected base claim, but contained allowable subject matter; and claims 45 - 52 were indicated as allowable.

In response, Applicants amended claims 1, 13, 22, 29, 35 and 40 and claims 53 - 89 were added: amended claim 1 corresponded to allowable claim 2, newly added claim 53 corresponded to allowable claim 3, newly added claim 64 corresponded to allowable claim 7, amended claim 13 corresponded to allowable claim 14, amended claim 22 corresponded to allowable claim 25, amended claim 29 corresponded to allowable claim 32, amended claim 35 corresponded to allowable claim 38, newly added claim 75 corresponded to allowable claim 39, and amended claim 40 corresponded to allowable claim 44. Thus, in accordance with the Office Action of 6 August 2001, claims 1, 3 – 13, 15 – 24, 26 – 31, 33 – 37, 39 – 43, and 45 – 78 were in condition for allowance.

However, in the second Office Action mailed 20 March 2002, rather than the forthcoming Notice of Allowance the pending 89 claims were subjected to a restriction requirement setting forth 19 "different species." In response, the Applicants elected claims 1 - 21.

In an Office Action mailed on 2 July 2002, claims 1 and 3 – 12 were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,916,193 to *Stevens et al.*; and claims 13 and 15 - 21 were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,643,303 to *Donahue*. In an Office Action mailed on 14 January 2003, claims 1 and 3 – 12 again were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,916,193 to *Stevens et al.*; and claims 13 and 15 - 21 again were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,643,303 to *Donahue*. The Office Action of 14 January 2003 was made final.

In this final rejection, the Office Action argued that "it is noted that the features upon which applicant relies (i.e. tissue engaging means and a handle assembly and an actuating means) are not recited in [claim 1 and its dependents]." In response to this final rejection, Applicants submitted an Amendment After Final on 6 March 2003 in which the tissue engaging means, handle assembly, and actuating means were recited in the body of claim 1 and its dependents. Nevertheless, on 1 April 2003 the Amendment After Final was refused.

After incurring the expense and delay of filing a continued examination request, an Office Action dated 23 June 2003 withdrew the previous rejections and entered a new grounds for rejection. Specifically, claims 1, 3-13, and 15-21 were rejected under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,474,057 to Makower et al.

Yet another final Office Action was entered 8 October 2003. Again the Examiner rejected claims 1, 3-13, and 15-21 under 35 U.S.C. § 103 as being unpatentable over U.S. Patent No. 5,474,057 to Makower et al. The Examiner relies on the disclosure of column 7 of Makower, quoting a portion which states that the tube "can be made out of any material appropriate for the nature of its use and in particular a medical grade plastics, metals . . .." to provide motivation to one in the art to make a kink resistant, fatigue resistant and has a bending radius. As discussed below, however, this argument takes out of context the quoted text and ignores the teachings of U.S. Patent No. 5,474,057 to Makower et al. as a whole.

Remarks

U.S. Patent No. 5,474,057 to Makower et al. ("*Makower*") describes a laparoscopic dissection tension retractor device. A retractor and dissector (10) for internal surgical use on a patient's body has a tubular support (11) for passing into the patient's body. A proximal end (12) on the tubular support is located outside the patient's body to provide access for the surgeon. A distal end (13) on the tubular support is located inside the patient's body to provide access within the patient for surgery. A control (19) is located at the proximal end of the tubular support. Articulated members (15) are movably positioned relative to the distal end of the tubular support so each of the articulated members allows swinging relative to the distal end. A rotator connects to the proximal end of the tubular support for movement relative to the control. An additional instrument moves independently of the tubular support when the articulated members and the distal tips cooperatively function on the tissue. The instrument passes simultaneously through a passage from the proximal end to beyond the distal end so the articulated members may position the tissue relative to the patient

The Office Action argues that *Makower* teaches that the "first tube [is] configured to be kink resistant and fatigue resistant and to bend about some bending radius in response to a bending movement applied to the first tube." In support for this conclusory allegation, the Office

Action cites Column 7, lines 4-16 of *Makower*. However, in Column 7, lines 4-16 do not support this allegation (with the Office Action's out of context quote *italicized*):

> "The tubular support 11 *can be made out of any material appropriate for the nature of its use and in particular a medical grade plastics, metals* **or ceramics** may be used, however, the choice of material will undoubtedly be determined by the function of the particular configuration. While elongate tube 41 can be easily extruded U-shaped channels 40, machining in addition to extrusion, or molding may be needed to obtain the desired cross-sectional configuration necessary. It is expected that skilled artisans will be able to fashion a tubular support 11 from single or multiple pieces in a way which provides a thin wall and allows a maximum passage 16 therethrough while providing adequate strength for carrying the members 15 at the distal end 13 thereof."

(Emphasis added). In the final office action of 8 October 2003, the Examiner argues that this text of *Makower* would motivate one skilled in the art to develop a kink and fatigue resistant device having a bending radius.

As this Board knows, the Supreme Court has expressly prohibited the use of hindsight to "read into the prior art the teachings of the invention in issue." *Graham v. John Deere Co.,* 383 U.S. 1, 36, 148 USPQ 459, 474 (1966). Any rejection must avoid the "hindsight gained from knowing that the inventor[s] choose to combine the particular things in this particular way." *Uniroyal Inc. v. Ruddin-Wiley Corp.*, 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988). In *In re Rijckaert*, 9 F.3d 1531, 1532, (Fed. Cir. 1993), the Federal Circuit outlined the burden on the PTO as follows:

"In rejecting claims under 35 U.S.C. 103, the examiner bears the initial burden of presenting a *prima facie* case of obviousness. *In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992). Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant. *Id.* "A *prima facie* case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art." *In re Bell*, 991 F.2d 781, 782, 26 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1993) (quoting *In re Rinehart*, 531 F.2d 1048, 1051, 189 U.S.P.Q. 143, 147 (CCPA 1976)). If the examiner fails to establish a *prima facie* case, the

rejection is improper and will be overturned. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988)."

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation to modify the prior art reference or to combine reference teachings. Second, there must be a reasonable expectation of success of achieving the desired goals. Finally, the prior art references when combined must teach ***all the claim limitations***. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

The Federal Circuit stated that the Patent Office can satisfy its burden of establishing a *prima facie* case of obviousness only by showing some objective teaching in the prior art, or that knowledge generally available to one of ordinary skill in the art, would lead that individual to combine the relevant teachings of the references. *In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992). One cannot use hindsight reconstruction to pick and choose among disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d at 1075. Here, this standard has not been met.

There is a complete absence of teaching of kink resistance and fatigue resistance in *Makower*. On this ground alone, the standard of obviousness has not been met and the rejection of claims 1, 3-13, and 15-21 should be overturned.

Moreover, *Makower* lists as an appropriate material ***ceramics***. To one of ordinary skill in the art, the inclusion of ceramics as an appropriate material ***teaches away from*** the claimed invention. The American Ceramics Society defines ceramics as typically crystalline in nature and formed between metallic and nonmetallic elements such as aluminum and oxygen (alumina-Al_2O_3), calcium and oxygen (calcia - CaO), and silicon and nitrogen (silicon nitride-Si_3N_4). Thus, the American Ceramics Society lists the characteristics of ceramics as:

- hard,
- wear-resistant,
- brittle,
- refractory,
- thermal insulators,
- electrical insulators,

- nonmagnetic,
- oxidation resistant,
- prone to thermal shock, and
- chemically stable.

http://www.ceramics.org. It is self evident that a hard, brittle, refractory, material is the very antithesis of a malleable material. Thus, *Makower* certainly does not disclose, suggest, or teach use of a malleable material as the first tube configured to be kink resistant and to bend about some bending radius in response to a bending moment applied to the first tube. Independent claims 1 and 13 both contain such claim limitations. Therefore, claims 1 and 13, as well as claims 3-12 and 15-21 which depend respectfully from them all recite patentable subject matter and are in condition for allowance.

CONCLUSION

Claims 1, 3-13, and 15-21 would not have be obvious in light of *Makower* to a person of ordinary skill in the art at the time the invention was made under 35 U.S.C. § 103(a). *Makower* does not teach, disclose, or suggest the use of a malleable material which is king resistant, fatigue resistant, and able to bend about a bending radius. Accordingly, favorable consideration and allowance of the application is respectfully requested.

Respectfully submitted,

Date 3-3-04

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APPENDIX

1. A surgical device comprising:

a tissue engaging means and a handle assembly;

an actuating means connecting the handle assembly and the tissue engaging means for actuating the tissue engaging means;

a shaft member comprising a first tube made of a malleable material and having a proximal end, a distal end and a longitudinal axis, the proximal end of the first tube adapted to be coupled to the handle assembly, the distal end of the first tube adapted to be coupled to the tissue engaging means, the actuating means adapted to extend axially through the first tube, the first tube configured to be kink resistant and to bend about some bending radius in response to a bending moment applied to the first tube.

3. The shaft member of claim 1 wherein the bending moment applied to the first tube ranges from between about 6 in-lbs to 27 in-lbs.

4. The shaft member of claim 1 wherein the bending momentum applied to the first tube ranges from about ¼ inch to 3/8 inch.

5. The shaft member of claim 1, wherein the first tub has a wall thickness and an outer radius extending fro the longitudinal axis of the first tube to an outer surface of the first tube, and wherein a ratio of the wall thickness to the square of the outer radius approximately ranges between about 2.0 and about 6.0.

6. The shaft member of claim 1, wherein the first tube is made of a material selected from the group consisting of stainless steel, copper, aluminum and brass.

7. The shaft member of claim 1, wherein the tube has a wall thickness ranging from approximately between 0.008 inches and 0.050 inches and an outside diameter ranging from approximately between 0.094 inches to 0.125 inches.

8. The shaft member of claim 1, wherein the proximal end of the first tube is adapted to be removably coupled to the handle assembly.

9. The shaft member of claim 1, wherein the distal end of the first tube is adapted to be removably coupled to the tissue engaging means.

10. The shaft member of claim 1, further comprising a second tube, the first tube coaxially aligned and disposed within the second tube.

11. The shaft member of claim 10, wherein the second tube is made of a material selected from the group consisting of aluminum, brass, copper and plastic.

12. The shaft member of claim 10, wherein the first tube and the second tube are formed as a co-extrusion.

13. A surgical device comprising:

a tissue engaging means including first and second opposed jaws for grasping, securing, and occluding body tissue and conduits;

a handle assembly;

an actuating means connecting the handle assembly and the tissue engaging means for actuating the tissue engaging means; and

a shaft member made of a malleable material and having a proximal end, a distal end and a longitudinal axis, the proximal end of the shaft member coupled to the handle assembly, the distal end of the shaft member coupled to the tissue engaging means, the actuating means extending axially through the shaft member, the shaft member configured to be kink resistant and to bend about some bending radius in response to a bending moment applied to the shaft member.

15. The surgical device of claim 13, wherein the bending moment applied to the shaft member ranges between 14 in-lbs to 15 in-lbs.

16. The surgical device of claim 13, wherein the shaft member has a wall thickness and an outer radius extending from the longitudinal axis of the shaft member to an outer surface of the shaft member, and wherein a ratio of the wall thickness to the square of the outer radius approximately ranges between 2.0 and 6.0.

17. The surgical device of claim 13, wherein the shaft member is made of a material selected from the group consisting of stainless steel, copper, aluminum and brass.

18. The surgical device of claim 13, wherein the proximal end of the shaft member is removably coupled to the handle assembly.

19. The surgical device of claim 13, wherein the distal end of the shaft member is removably coupled to the tissue engaging means.

20. The surgical device of claim 13, further comprising an outer tube, the shaft member coaxially aligned and disposed within the outer tube.

21. The surgical device of claim 20, wherein the outer tube is made of a material selected from the group consisting of aluminum, brass, copper and plastic.